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UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN JOSE DIVISION

UNITED STATES OF AMERICA,  
  
Plaintiff,  
  
v.  
  
HOLMES, et al.,  
  
Defendants.

Case No. 18-CR-00258-EJD

**DEFENDANT RAMESH BALWANI'S  
OPPOSITION TO UNITED STATES'  
MOTION TO EXTEND DEADLINE BY  
WHICH TO COMPLY WITH COURT'S  
NOVEMBER 5, 2019, ORDER**

Date: January 13, 2020  
Time: 10:00 a.m.  
Judge: Honorable Edward J. Davila  
Courtroom: 4, 5th Floor

After being granted multiple chances to fulfill its discovery obligations with respect to FDA documents over at least the entire second half of 2019, the government now throws up its hands and admits it is in violation of the Court's November 5, 2019 Order (Dkt. No. 174) and unable to comply. As it sinks under the weight of this problem of its own making, the government's eleventh-hour motion to extend time attempts to shift blame to the defense. The government's failure to hold itself accountable is unavailing, and in any event reliant on a series of inaccurate assertions about supposed defense "demands." The bottom line is that after months of claiming that the production was complete or nearly complete in briefing and argument before this Court, the government now says that the FDA will not send all documents to the DOJ until around April 30, 2020, meaning that the defense would not get all documents as ordered by the Court until the summer.

The government's failure to comply with the Court's Order continues to prejudice the defense's ability to prepare for trial and jeopardizes the case schedule set by the Court. The defense has done everything possible to facilitate the timely production of FDA documents, including agreeing to a severe protective order and taking on considerable burdens to satisfy the FDA's disclosure concerns. Surely the United States Government can find a way to comply with the Court's order to stem the ongoing prejudice to the defense and the case schedule.

# **I. THE GOVERNMENT HAS HAD EVERY OPPORTUNITY TO COMPLY WITH THE COURT'S ORDERS**

The government's violation of the Court's November 5 Order is a problem of its own making. The government has received multiple extensions of time and has had every chance to comply. The defense's motion to compel was filed almost nine months ago (the civil subpoena issued about 16 months ago<sup>1</sup>), and the Court ordered all responsive documents to be produced by October 2, 2019 (Dkt. No. 111), then by October 25, 2019 (Dkt. No. 134), and then again by December 31, 2019 (Dkt. No. 174). At each juncture, the government claimed the FDA had

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<sup>1</sup> The FDA should have been collecting documents from the time that Mr. Balwani served an SEC subpoena on the agency, in September 2018, so the FDA is now going on 16 months without complying with its discovery obligations. The civil subpoena was broader than the six categories of documents in this case, but prior to beginning production based on the motion to compel, the FDA had produced less than 200 documents.

1 complied or nearly complied,<sup>2</sup> but each time that turned out not to be the case. As a result, the  
 2 Court ordered the DOJ to formally take over the process under Rule 16, and to produce all  
 3 documents by the end of 2019.

4 Now, the day before the Court's deadline, the government cavalierly represents that the  
 5 FDA *may* have all the data collected and to the DOJ by April 30, 2020. Dkt. No. 215 ("Mtn.") at  
 6 5:25-26. It is not clear why the DOJ is continuing to rely so heavily on FDA personnel in view of  
 7 the past difficulties. The DOJ has vast resources, and many skilled attorneys and staff  
 8 experienced with enormous document productions. Yet it has chosen to continue to rely on FDA  
 9 staff, an agency with less experience with document productions, to take the laboring oar. When  
 10 the defense bar must respond to DOJ subpoenas, including on behalf of large corporate clients, it  
 11 often hires experienced vendors and processes millions of pages for production to the United  
 12 States. The government typically has little tolerance for complaints about resource utilization and  
 13 costs, even when a defendant's right to fair trial is not at stake. The DOJ can do the same here.

14 Under the government's proposal, the government would not satisfy the Court's order to  
 15 provide all documents to the defense until at least May 2020, and more likely later in the summer,  
 16 at which time the defense still will need to review the documents, work with the government to  
 17 redact third-party trade secret material under the Fourth Supplemental Protective Order (Dkt.  
 18 No. 214), and litigate any remaining compliance issues before the trial is set to begin on July 28,  
 19 2020. This is unworkable. In fact, the government recognized that the FDA's proposal to  
 20 produce documents by January 2020 was unworkable,<sup>3</sup> but now wants at least an additional four  
 21 to six months beyond even that timeframe.

23 \_\_\_\_\_  
 24 <sup>2</sup> See e.g., Transcript of Proceedings Before the Honorable Edward J. Davila, (10/2/2019) at 4:10-14 (Mr. Bostic:  
 25 "My understanding is that ... the agencies are still on track to complete their productions of responsive  
 26 documents either today or in the very near future."); *id.* at 4:23-5:1 (Mr. Bostic: "The government's  
 understanding is that the defense will have all novel, nonduplicative and discoverable information either today or  
 within the next few days."); Dkt. No. 121 at 3 (September 30, 2019 Joint Status Memo) ("As to FDA, the agency  
 expects to be in substantial compliance with the Court's order as of October 2.").

27 <sup>3</sup> In July 2019, the prosecution agreed that the FDA's proposed 6-month time frame to complete the production by  
 28 January 2020 was "unacceptable." Dkt. No. 89 at 3:14-16 ("For its part, FDA estimates that its production of all  
 responsive documents may take as long as six months. Defendants have objected to this schedule, and the  
 prosecution shares the view that such delay is unacceptable.").

1 **II. THE DEFENSE HAS DONE EVERYTHING POSSIBLE TO FACILITATE**  
 2 **PRODUCTION**

3 Since the Court's November 5 Order, the defense has done everything it could to facilitate  
 4 timely production, including by accommodating the government's request for an extraordinary  
 5 protective order that places enormous burdens on the defense to screen documents for any trade  
 6 secrets material and interferes with the ability to communicate with the defendants until that  
 7 screening occurs. Dkt. No. 214. During the meet and confer process, the defense also  
 8 accommodated the government's requests for additional guidance on search terms and custodians  
 9 that might be appropriate. Coopersmith Decl. ¶ 2. The defense was surprised to receive the  
 10 government's motion for a lengthy continuance, especially because the government did not give  
 11 the defense any notice that its production would be substantially delayed. *Id.* ¶¶ 8-9. In fact, the  
 12 defense believed the government was on track to complete its production when it informed  
 13 Mr. Balwani that he could expect a large production of documents on December 31, *id.* ¶ 9, Ex.  
 14 C, but then filed its motion to extend a day before the deadline.

15 The defense has played no part in this delay, and the government's motion is rife with  
 16 factual inaccuracies. First, the government accuses Mr. Balwani of insisting "that 55 additional  
 17 custodians' documents be electronically searched," suggesting this may somehow be a reason for  
 18 the government's delay. Mtn. at 4:9-10. However, after the Court's November 5 Order, the  
 19 prosecution asked the defense for a list of custodians whose records should be searched to comply  
 20 with the Court's Order. Coopersmith Decl. ¶ 2. The government omits that Mr. Balwani  
 21 provided the prosecution with the same list of 67 FDA custodians that FDA's counsel (an AUSA  
 22 from the same office as the prosecution team) gave the parties on October 4, 2019. *Id.* ¶ 3, Ex. B.  
 23 Mr. Balwani did not add 55 custodians; rather, he gave the DOJ the same custodians that the FDA  
 24 had already identified, and added eleven additional custodians based on his review of the  
 25 productions thus far. *Id.* ¶ 3. The government was aware of these custodians long before  
 26 Mr. Balwani's counsel sent the government's own list of custodians to the U.S. Attorney's Office.  
 27 While the government asserts that the defense created new obligations on the government after  
 28 the Court's November 5 Order, Mtn. at 2, that is simply not so. The government has known of its

1 obligations for many months. The government is simply paying the price now for its attempt to  
2 take a hands-off approach to documents of which it has had access and knowledge.

3 Second, the government also suggests that the defense has added search terms and  
4 expanded the Court's Order. Mtn. at 3. To the contrary, the defense has been insisting that the  
5 government use the search terms directed by the Court. Coopersmith Decl. ¶¶ 4-6. The only  
6 search term that the defense has added is "Holmes," to catch communications about  
7 Mr. Balwani's co-defendant Elizabeth Holmes. *Id.* ¶ 5. Mr. Balwani also requested that the  
8 government search for commonly-used variations on the search terms ordered by the Court, such  
9 as "Lab-developed test"—which is often used as an alternative to "Laboratory Developed Test."  
10 *Id.* ¶ 5. In addition, the government previously informed Mr. Balwani that certain search terms  
11 (listed at Mtn. at 3:11-15) were used to collect documents from "*certain*," but *not all* the FDA  
12 custodians. Mr. Balwani requested that the FDA search *all* of the appropriate FDA custodians  
13 using these terms, as the government itself had determined that those custodians might have  
14 responsive documents. *Id.* ¶¶ 4, 6. These requests were all within the scope of the Court's Order,  
15 which requires production of *all* responsive documents. It is flatly incorrect to suggest that the  
16 defense somehow expanded the Court's Order and caused delay.

17 Third, the government claims "the defense appears to insist that any form of manual  
18 search is insufficient." Mtn. at 6:3-4. During a meet and confer after the Court's Order, the  
19 prosecution informed the defense that it was going to perform electronic collections from all  
20 custodians. Coopersmith Decl. ¶ 7. The defense was never aware of any disagreement on this  
21 issue, and is surprised to be hearing about one for the first time. *Id.* The government's motion is  
22 also the first time the defense learned that the government, for some unidentified reasons, needs  
23 to manually collect from 23 individuals "under the supervision of FDA attorneys." *Id.*; Mtn. at 6-  
24 7. If the government had raised these issues with the defense and explained its reasoning,  
25 Mr. Balwani would have asked for more detail and, depending on the explanation,<sup>4</sup> might have  
26 agreed to manual collection for these specific custodians under the supervision of DOJ (not FDA)

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27 <sup>4</sup> Prior manual collection practices at FDA were clearly insufficient, as they omitted vast swaths of relevant  
28 materials.

attorneys. Similarly, if the government had kept Mr. Balwani apprised of its need for Agent Scavdis to collect his own documents, and assured the defense that the prosecution was supervising his collection, Mr. Balwani would not have objected and does not object to that now.

In short, the government's attempt to shift blame to the defense instead of taking accountability here is misplaced. The current situation is simply the product of the government's ill-advised decision to take a hands-off approach to the production of critical documents from the FDA.

### **III. THE GOVERNMENT'S PROPOSED TIMELINE IS UNACCEPTABLE**

The government has now failed to meet three deadlines, and should be ordered to produce the documents forthwith to avoid further prejudice to the defense and the schedule. At this late stage, any further delay by the government continues to compromise the defense's ability to prepare for trial and defend this case. The government is already in violation of the Court's Order and will continue to be every day that goes by without full compliance, which may prove to be a motivating factor.

### **IV. CONCLUSION**

For the foregoing reasons, the Court should deny the government's motion for an extension.

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